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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,657	08/05/2003	Chieh-Fu Chen	3358-0145P	5467

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/31/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/633,657	CHEN ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006 and 28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 28, 2006 has been entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 5 has been added.

3. Claims 1-5 are currently pending.

4. In the reply filed on December 14, 2005, applicant elected Group I without traverse.

5. Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 14, 2005.

6. Claims 1 and 3-5 are examined on the merits.

Claim Objections

7. Claim 5 objected to because of the following informalities: in line 3, "limit" should be "limits" and "were" should be "are". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 1 and 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the final rejection of August 25, 2006.

As discussed in the previous Office action, the phrase "specially processed" is indefinite. Applicant argues that this term is definite because the method for preparing the extract has been set forth in the claim. However, the term "special" is considered to be a narrative term which is inconsistent with U.S. practice. It is unclear how this term is defining the product. It is unclear if the use of "special" is intended to confer a further limitation on the claimed product. Thus, the use of "special" is considered indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to state that the *Stephaniae tetrandrae* is extracted at 60 degrees C. However, the specification only shows extraction at 80 degrees C (see Examples 1-6). Thus, there is no support for extraction at the claimed temperature.

Claim Rejections - 35 USC § 102/103

10. Claims 1 and 3-5 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chou et al. (Journal of Chinese Medicine (March 2002), vol. 13, no. 1, pp. 39-48).

Claims 1 and 3-5 are product-by-process claims. Regarding product-by-process claims, note that MPEP § 2113 states that:

> "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

Chou teaches an extract from *Stephania tetrandra* roots that contain tetrandrine, fangchinoline, cyclanoline, and oblongine. The extract is created by extracting the roots with 95% ethanol 3 or 5 times at 80 degrees Celsius (see page 41, "Experimental" section). The reference discloses extract which appears to be identical to the presently claimed extract, based on the fact that the both the reference extract and the claimed extract are *S. tetrandra* extracts

created using multiple ethanolic extraction and both contain tetrandrine, fangchinoline, cyclanoline, and oblongine. Furthermore, figure 2 of Chou shows the HPLC data which show the retention times for tetrandrine, fangchinoline, cyclanoline, and oblongine. The HPLC times shown in Chou are similar if not identical to those claimed by applicant in claim 5. This further supports a conclusion that the composition of Chou is the same composition. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared components.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

This is technically a new ground of rejection. However, applicant's arguments regarding Chou have been considered to the extent that they apply to this new ground of rejection. Applicant argues that the reference does not teach the stated claims because Chou does not teach that the extract has other compounds with biological activity. However, Chou teaches that tetrandrine, fangchinoline, cyclanoline, and oblongine are naturally present in any ethanolic sample from the *S. tetrandra* root and in any root material from this plant at all. Applicant's specification teaches that the additional biological components are soluble in ethanol. Thus, the ethanolic extracts of the reference would naturally contain additional components as claimed by applicant. *Furthermore, the extract taught by Chou contains ethanol which has biological*

activity. Applicant has not claimed specific additional components; thus, the inclusion of ethanol is considered to teach this limitation of applicant's claims.

Applicant also argues that the reference does not teach the same levels of tetrandrine and fangchinoline as in applicant's extract. However, the claims do not specify specific amounts of these compounds. The HPLC data claimed by applicant does not confer concentrations. Thus, the reference is still considered to properly anticipate the stated claims. In addition, applicant argues that the claimed composition has lower toxicity and increased antiinflammatory activity. However, the composition of Chou appears to be the same as the claimed composition for the reasons discussed above. Thus, the composition of Chou would inherently have the same biological properties. In addition, if the composition of Chou is not identical, applicant needs to provide some proof that the compositions are not the same as discussed in MPEP section 2113.

11. Claims 1 and 3-5 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Pat. No. 6,218,541.

US '541 teaches an extract from *S. tetrandra* roots. The reference specifically teaches that the extract contains tetradrine, fangchinoline and cyclanoline (see figure 1). The extract is made by extracting the roots once with 95% ethanol (see bottom paragraph of column 2). The reference does not specifically teach that oblongine is present. However, according to applicant's specification, this component is naturally present in *S. tetrandra* roots and is soluble in ethanol. Thus, oblongine would inherently be present in the ethanolic extract of US '541.

The reference discloses extract which appears to be identical to the presently claimed extract, based on the fact that the both the reference extract and the claimed extract are *S.*

tetrandra extracts created using ethanolic extraction and both contain tetrandrine, fangchinoline, and cyclanoline. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared components.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

This is technically a new ground of rejection. However, applicant's arguments regarding this reference have been considered to the extent that they apply to this new ground of rejection. Applicant argues that the reference does not teach that there are additional compounds with biological activity in the *S. tetrandrae* root extract. However, applicant's specification teaches that any additional biological components are soluble in ethanol. Thus, these components would also be present in the ethanolic extract taught by the reference.

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHoffman
1-22-07

Susan Coe Hoffman
Primary Examiner
Art Unit 1655